

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | |
|------------------------------|---|--------------------------|
| In re Application of |) | |
| |) | |
| Sandig et al. |) | Art Unit: 1651 |
| |) | |
| Application No. 10/530,224 |) | Examiner: Barnhart, L.E. |
| |) | |
| Filing Date: July 21, 2005 |) | Confirmation No. 1743 |
| |) | |
| For: HIGH YIELD HETEROLOGOUS |) | |
| EXPRESSION CELL LINES FOR |) | |
| EXPRESSION OF GENE PRODUCTS |) | |
| WITH HUMAN GLYCOSYLATION |) | |
| PATTERN |) | |

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

NEEDLE & ROSENBERG, P.C.
Customer Number 23859

Sir:

This is in response to the Office Action dated January 09, 2008, wherein restriction of the claims of the above-identified application is required. A Request for Extension of time is included herewith.

The Office Action requires restriction to one of the following two groups of claims:

Group I: Claims 18-50, drawn to a process for preparing a cell capable of stable high-yield expression of a target gene product, the product of the process, and a method of using the product;

Group II: Claims 52 and 53, drawn to a protein.

As required in response to the Restriction Requirement, Applicants provisionally elect Group I (claims 18-50) without traverse.

The Office Action further requires election of a manner of inserting DNA coding for the target gene product from among the following:

- (a) replacing the gene coding for the Ig with a first functional sequence containing one or more RRSs and then integrating a second functional DNA sequence comprising a DNA sequence that codes for the target gene product into the functionalized precursor cell by use of a recombinase recognizing the RRSs; and
- (b) directly replacing the gene coding for the Ig with a DNA sequence that codes for the target gene product.

As required in response to the Restriction Requirement, Applicants provisionally elect species (a) with traverse.

The Office Action further requires election of starting cells from among the following:

- (c) human myeloma;
- (d) human hybridoma; and
- (e) human hetero-hybridoma.

As required in response to the Restriction Requirement, Applicants provisionally elect species (e) with traverse.

The Office Action further requires election of sites of integration of the functional DNA sequences from among the following:

- (f) at a rearranged Ig locus;
- (g) at a rearranged IgH locus; and
- (h) at a lambda locus.

As required in response to the Restriction Requirement, Applicants provisionally elect species (g) with traverse.

The Office Action further requires election of methods of identifying the Ig locus from among the following:

- (i) microarray expression analysis;
- (j) 2D protein gel electrophoresis;
- (k) quantitative PCR;
- (l) RNase protection;

- (m) Northern blot;
- (n) ELISA; and
- (o) western blot.

As required in response to the Restriction Requirement, Applicants provisionally elect species (n) with traverse.

The Office Action further requires election of RRSs from among the following:

- (q) loxP;
- (r) frt;
- (s) attL and attR sites of lambdoid phages;
- (t) recognition sites for resolvases;
- (u) recognition sites for phage C31 integrase;
- (v) modified loxP; and
- (w) modified frt.

As required in response to the Restriction Requirement, Applicants provisionally elect species (r) with traverse.

The Office Action further requires election of additional features from among the following:

- (x) marker sequences;
- (y) secretion proteins;
- (z) promoters;
- (a') enhancers;
- (b') splice signals;
- (c') polyadenylation signals; and
- (d') IRES elements.

As required in response to the Restriction Requirement, Applicants provisionally elect species (y) with traverse.

The Office Action further requires election of target gene products from among the following:

- (e') enzymes;
- (f') hormones;
- (g') cytokines;
- (h') receptors;
- (i') antibodies;
- (j') antibody fragments;
- (k') fusion proteins comprising enzymes;
- (l') fusion proteins comprising hormones;
- (m') fusion proteins comprising cytokines;
- (n') fusion proteins comprising receptors;
- (o') fusion proteins comprising antibodies; and
- (p') fusion proteins comprising antibody fragments.

As required in response to the Restriction Requirement, Applicants provisionally elect species (i') with traverse.

The Office Action further requires election of second functional DNA sequences from among the following:

- (q') promoter sequences;
- (r') marker sequences;
- (s') splice donor and acceptor sequences; and
- (t') RRSs;

As required in response to the Restriction Requirement, Applicants provisionally elect species (t') with traverse.

The Office Action posits that the listed species do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features. To support this position, the Office action cites PCT Administrative Instructions, Annex B, Part 1(f)(l)(B)(2) relating to Markush Practice, which states

“When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where ... all alternatives have a common property or activity, and ... a common structure is present ... or ... in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains ...” (emphasis added)

The Office action then argues that the species are not art-recognized equivalents.

First, Applicants are not aware of any authority for requirement of species elections under PCT Rule 13.2. Moreover, PCT Administrative Instructions, Annex B, Part 1(f)(l)(B)(2) relating to Markush Practice is not correctly applied in the Office Action. These instructions assume that the single claim is not dependent from another claim that does include a common technical feature. It does not further require that each recited element of the Markush group also have a common technical feature over and above that of the claim from which it depends.

Accordingly, PCT Administrative Instructions, Annex B, Part 1(c) relating to Independent and Dependent Claims, states “Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims... If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims...”

As the Office Action has not cited any prior art in relation to the novelty of claim 18, these requirements for election of species in dependent claims is unjustified.

Favorable consideration of claims 18-51 is earnestly solicited.

ATTORNEY DOCKET NO. 04156.0012U1
Application No. 10/530,224

A Credit Card Payment submitted via EFS web authorizing payment in the amount of \$1,115.00, representing the fee for a small entity under 37 C.F.R. § 1.17(a)(5) for a Five Month Extension of Time, and a Request for Extension of Time are hereby enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.


Respectfully submitted,

NEEDLE & ROSENBERG, P.C.



P. Brian Giles, Ph.D.
Registration No. 57,896

NEEDLE & ROSENBERG, P.C.
Customer Number 23859
(678) 420-9300
(678) 420-9301 (fax)

| CERTIFICATE OF ELECTRONIC TRANSMISSION UNDER 37 C.F.R. § 1.8 | | | |
|---|---|------|-----------|
| I hereby certify that this correspondence, including any items indicated as attached or included, is being transmitted via electronic transmission via EFS-Web on the date indicated below. | | | |
| Name of Person Mailing (Print/Type) | P. Brian Giles, Ph.D. | | |
| Signature |  | Date | 6-16-2008 |